

Form PTO-1449

U.S. Department of Commerce
Patent and Trademark OfficeAtty. Docket No.
1747/55293-B-PCT-
US/JPW/AJM/MVMSerial No.
10/009,861

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Applicant
Carlos Cordon-Cardo et al.Filing Date
December 10, 2001Group
1634

U.S. PATENT DOCUMENTS

Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate

FOREIGN PATENT DOCUMENTS

	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No
	WO 9 9 0 4 2 3 8	1/28/99	PCT				
	WO 9 8 3 3 4 5 0	5/6/98	PCT				
	WO 9 4 2 2 4 7 8	10/13/94	PCT				
	WO 9 9 3 1 1 4 0	6/24/99	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

See	Aaltomaa, S. et al. (1999) "Prognostic Value and Expression of p21 (waf1/cip1) Protein in Prostate Cancer" <i>The Prostate</i> , 39(1):8-15;
	Agus, D.B. et al. (1999) "Response of Prostate Cancer to Anti-HER-2/neu Antibody in Androgen-Dependent and -Independent Human Xenograft Models" <i>Cancer Research</i> , 59(1):4761-4764;
	Arai, Y. et al. (1997) "C-erbB-2 Oncoprotein: A Potential Biomarker of Advanced Prostate Cancer" <i>Prostate</i> , 30(3):195-201;
	Baretton, G.B. et al. (1999) "Proliferation- and Apoptosis-Associated Factors in Advanced Prostatic Carcinomas Before and After Androgen Deprivation Therapy: Prognostic Significance of p21/WAF1/CIP1 Expression" <i>British Journal of Cancer</i> , 80(3-4):546-555;
	Baselga, J. et al., (1998) "Recombinant Humanized Anti-HER2 Antibody (Herceptin TM) Enhances the Antitumor Activity of Paclitaxel and Doxorubicin Against HER2/neu Overexpressing Human Breast Cancer Xenografts" 58(13):2825-2831;

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Applicants: Carlos Cordon-Cardo et al.
Serial No.: 10/009,861
Filing Date: December 10, 2001
Exhibit A

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su	Cariou S. et al. (1998) "Prognostic Implication of Expression of the Cell Cycle Inhibitor Protein P27", <i>Breast Cancer Research and Treatment</i> , 1-3(52):29-41;
	Cordon-Cardo Carlos, et al. (1998) "Distinct Altered Patterns of p27 ^{KIP1} Gene Expression in Benign Prostatic Hyperplasia and Prostatic Carcinoma" <i>J. Natl. Cancer Inst.</i> 90(17): 1284-1291;
	Cote, R.J. et al. (1998) "Association of p27 ^{KIP1} Levels With Recurrence and Survival in Patients With Stage C Prostate Carcinoma" <i>J. Natl. Cancer Inst.</i> 90(12): 916-920;
	Chen, Y. et al. (1998) "Increased Cell Growth and Tumorigenicity in Human Prostate LNCaP Cells by Overexpression to Cyclin D1" <i>Oncogene</i> , 16(15):1913-1920;

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See	Craft, N. et al., (1999) "A Mechanism for Hormone-Independent Prostate Cancer Through Modulation of Androgen Receptor Signaling by the HER-2/neu tyrosine Kinase" <i>Nature Medicine</i> , 5(3):280-285;
	Curnow, R.T. et al., (1997) "Clinical Experience With CD64-Directed Immunotherapy. An Overview" <i>Cancer Immunology And Immunotherapy</i> , 45(3-4):210-15;
	Database Biosis [Online] Biosciences Information Service, Philadelphia, PA, US (1999-03) Lee Tae Yoon et al., "Immunohistochemical Expression of p53 and MDM-2 Protein in Various Epithelial Carcinomas" Database Accession No. PREV1999900406745;
	DeMarzo, A.M. et al. (1998) "Prostate Stem Cell Compartments: Expression of the Cell Cycle Inhibitor p27kip1 in Normal, Hyperplastic, and Neoplastic Cells" <i>Amer. J. Path.</i> 153(3): 911-919;

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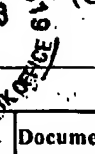
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

SM	James, N. et al., (1998) "Phase II Trial of the Bispecific Antibody MDX-H210 (Anti-Her2/Neu X Anti-CD64) Combined With GM-CSF In Patients With Advanced Prostate and Renal Cell Carcinomas That Express Her2/Neu" <i>British Journal of Cancer</i> , 78(Suppl 2):19;
↓	Koeneman, K.S. et al., (1999) "Osteomimetic Properties of Prostate Cancer Cells: A Hypothesis Supporting the Predilection of Prostate Cancer Metastasis and Growth in the Bone Environment" <i>Prostate</i> , 39:246-261;
↓	Lee, C.T. et al., (1999) "Overexpression of the Cyclin-Dependent Kinase Inhibitor P16 is Associated with Tumor Recurrence in Human Prostate Cancer" <i>Clinical Cancer Research, The American Association for Cancer Research, US</i> , 5(5):977-983;

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



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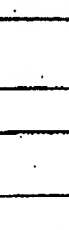
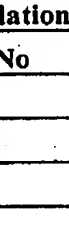
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
	Lloyd et al. (1999) "P27 ^{kip1} : a Multifunctional Cyclin-dependent Kinase Inhibitor with Prognostic Significance in Human Cancers" <i>American J. Pathology</i> 154(2): 313-323;
	McArthur, J.G. et al. (1999) "Cancer Gene Therapy with Novel Chimeric P27/p16 Tumor Suppressor Genes" <i>Proceed. Amer. Assoc. Cancer Res. Ann.</i> 40: 630;
	Osman, I. et al. (1999) "Inactivation of the p53 Pathway in Prostate Cancer: Impact on Tumor Progression" <i>Clinical Cancer Research: An Official Journal of the American Association for Cancer Research</i> , 5(8):2082-2088;
	Ross, J.S. et al., (1993) "Contribution of HER-2/neu Oncogene Expression to Tumor Grade and DNA Content Analysis in the Prediction of Prostatic Carcinoma Metastasis" <i>Cancer</i> , 72(10):3020-3028;

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cu	Veltri, R. et al. (1994) "Quantitative nuclear morphometry, Markovian Texture Descriptors, and DNA content Captured on a CAS-200 Image Analysis Systems, Combined With PCNA and HER-2/neu Immunohistochemistry for Prediction of Prostate Cancer Progression" <i>Journal of Cellular Biochemistry</i> , 19:249-258;
	Yamasaki, I. et al. (1996) "Overexpression of MDM2 and p53 Protein is Infrequently but Significantly Associated With Progression of Human Prostatic Adenocarcinoma" <i>Oncology Reports</i> , 3(5):925-929 and
↓	Zhau, H. et al. (1992) "Expression of C-erb B-2/neu Proto-Oncogene in Human Prostatic Cancer Tissues and Cell Lines" <i>Molecular Carcinogenesis</i> , 5(4): 320-327.

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	6 3 1 6 2 0 8	11/13/01	Roberts et al.			
	5 6 8 8 6 6 5	11/18/97	Massague et al.			RECEIVED
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FOREIGN PATENT DOCUMENTS

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✓ WO	9 9 0 4 2 3 8	01/28/99	PCT (Exhibit 1)			✓	
✓ WO	9 8 3 3 4 5 0	08/6/98	PCT (Exhibit 2)				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

1. Agus, D.B., et al. (1999) "Response of Prostate Cancer to Anti-Her-2/neu Antibody in Androgen-dependent and -independent Human Xenograft Models" Cancer Res. 59: 4761-4764;

2. Agus, D.B. et al. (1999) "Prostate Cancer Cell Cycle Regulators: Response to Androgen Withdrawal and Development of Androgen Independence" J. Natl. Cancer Inst. 91(21): 1869-1876;

3. Aprikian, A.G., et al. (1994) "Immunohistochemical Determination of P53 Protein Nuclear Accumulation in Prostatic Adenocarcinoma" J. Urol. 151: 1276-1280;

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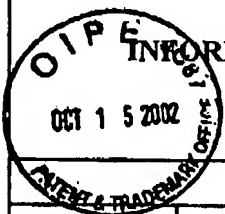
Bibliography (including Author, Title, Date, Pertinent Pages, Etc.)	
CM	Campbell, M.J., et al. (1997) "Inhibition of Proliferation of Prostate Cancer Cells by a 19-nor-hexafluoride Vitamin D ₃ Analogue Involves the Induction of p21 ^{waf1} , p27 ^{kip1} and E-cadherin" <u>J. Mol. Endocrin.</u> 19: 15-27;
	Cohen, D.W., et al. (1994) "Expression of Transforming Growth Factor- α and the Epidermal Growth Factor Receptor in Human Prostate Tissues" <u>J. Urol.</u> 152: 2120-2124;
	Cordon-Cardo, Carlos, et al. (1998) "Distinct Altered Patterns of p27 ^{kip1} Gene Expression in Benign Prostatic Hyperplasia and Prostatic Carcinoma" <u>J. Natl. Cancer Inst.</u> 90(17): 1284-1291;
	Cote, R.J., et al. (1998) "Association of p27 ^{kip1} Levels With Recurrence and Survival in Patients With Stage C Prostate Carcinoma" <u>J. Natl. Cancer Inst.</u> 90(12): 916-920;

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8	9	10	11	12	DeMarzo, A.M., et al. (1998) "Prostate Stem Cell Compartments: Expression of the Cell Cycle Inhibitor p27kip1 in Normal, Hyperplastic, and Neoplastic Cells" <u>Amer. J. Path.</u> 153(3): 911-919 (Exhibit 3);
					DiCristofano, A., et al. (1998) "Pten Is Essential for Embryonic Development and Tumour Suppression" <u>Nature Genetics</u> 19: 348-355;
					Fernandez, P.L. et al. (1999) "Expression of p27/kip1 Is Down-regulated in Human Prostate Cancer Progression" <u>J. Path.</u> 187(5): 563-566 (Exhibit 4);
					Guo, Y., et al. (1997) "Loss of the Cyclin-dependent Kinase Inhibitor p27 ^{kip1} Protein in Human Prostate Cancer Correlates with Tumor Grade" <u>Clin. Cancer Res.</u> 3: 2269-2274;
					Hengst, L., et al. (1996) "Translational Control of p27 ^{kip1} Accumulation During the Cell Cycle" <u>Science</u> 271: 1861-1864;

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22	See	Polyak, K., et al. (1994) "Cloning of p27 ^{Kip1} , a Cyclin-Dependent Kinase Inhibitor and a Potential Mediator of Extracellular Antimitogenic Signals" <u>Cell</u> 78: 59-66;
23		Polyak, K., et al. (1994) "p27 ^{Kip1} , a Cyclin-Cdk Inhibitor, links transforming growth factor- β and contact inhibition to cell cycle arrest" <u>Genes & Development</u> 8: 9-22;
24		Scher, H.I., et al. (1995) "Changing Pattern of Expression of the Epidermal Growth Factor Receptor and Transforming Growth Factor α in the Progression of Prostatic Neoplasms" <u>Clin. Cancer Res.</u> 1: 545-550;
25		Silver, D.A., et al. (1997) "Prostate-specific Membrane Antigen Expression in Normal and Malignant Human Tissues" <u>Clin. Cancer Res.</u> 3: 81-85; and
26	✓	Simak, R., et al. (2000) "Expression of C-kit and Kit-ligand in Benign and Malignant Prostatic Tissues" <u>Histol. Histopathol.</u> 15: 365-374.

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